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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,969	07/21/2005	Tomoharu Suga	44342.024000	2010

7590 11/13/2008  
GERARD F DIEBNER  
DREIER LLP  
499 PARK AVENUE  
NEW YORK, NY 10022

EXAMINER
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AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,969	<b>Applicant(s)</b> SUGA ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicants' RCE filed on 20 August 2008.

\* \* \* \* \*

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 2 July 2008 has been entered.

\* \* \* \* \*

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto, et. al. (U.S. Patent No. 5,576,014).

Mizumoto, et. al. disclose an intraorally rapidly disintegrating tablet (see col. 1, lines 9-28).

The disclosed tablet is the instant tablet as claimed:

- the active ingredient mixed with a sugar of instant claim 6 (see col. 12, lines 24-26);
- the core granule coated with a pharmaceutical disintegrating agent of instant claims 6 and 7 (see col. 7, lines 19-46; col. 13, lines 39-43);
- the active ingredient of instant claims 6 and 7 (see col. 12, lines 23-26);
- the “substantially complete” covering of instant claims 6 and 7 (*i.e.* the high moldability saccharide coating (see col. 13, lines 5-7) mixed with disintegrating agents (see col. 13, lines 36-41 and lines 58-65);
- the disintegrating agent of instant claims 2 and 8 (see col. 13, line 40);
- the sugar of instant claim 3 (see col. 7, lines 19 and 20);
- the average particle diameter of instant claims 4 and 9 (see col. 7, lines 50 and 51); and
- the tablet thickness of instant claims 5 and 10 (see col. 5, line 37).

\* \* \* \* \*

### ***Response to Arguments***

Applicants’ arguments filed 2 July 2008 have been fully considered and are not persuasive.

1. Applicants argue that, “...persons skilled in the art would not try to add the disintegrating agent to a coating solution...and would not understand that the disintegrating agent should be added to a coating solution.” See remarks, page 2.

The instant specification discloses a coating comprising a mixture of water, a binding agent, a sugar, and a disintegrating agent (see examples 1-12). Mizumoto

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similarly discloses a coating comprising a mixture of water, a binding agent, a sugar, and a disintegrating agent (see col. 13, lines 3-7, 36-43, and 58-65). Applicants are not claiming any particular concentration of disintegrating agent, or any particular ratio of disintegrating agent to water.

The disintegrating agents are the same as those instantly claimed, i.e. potato starch, corn starch, and carboxymethylcellulose calcium (see col. 13, lines 40-41). These agents are referred to as “disintegrating agents” as opposed to “fillers” or “excipients”, thus the plain language of the disclosure indicates that said agents are intended to facilitate disintegration of the granule when exposed to the buccal cavity.

Mizumoto states that, “[t]he preparation of the present invention may contain various additive agents generally used in the production of tablets so long as they do not spoil the effects of the present invention.” See col. 13, lines 32-38. The effects of the Mizumoto invention, as stated throughout the reference, is “quick disintegration and dissolution in the buccal cavity.” See abstract. As such, examiner respectfully submits that the Mizumoto invention is consistent with the instant disclosure. The addition of a disintegrating agent to the Mizumoto invention facilitates quick disintegration and dissolution in the buccal cavity. Thus Mizumoto is using the same ingredients as the instant application for the same purpose as the instant disclosure.

2. Applicants argue that the method of using the disintegrating agent in the instant application differs from that of Mizumoto's invention. See remarks, page 2.

Examiner respectfully submits that the rejected claims are product claims, not method claims. Although the claims are interpreted in light of the specification,

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limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

★

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1618

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/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615